

World first COVID-19 vaccine booster study launches in UK

- Initial results trialling seven vaccines expected in September to inform plans for booster programme
- Clinical trials on agenda for G7 Health Ministers' Meeting in early June which Health Secretary announces will be hosted in Oxford
- Announcements come ahead of International Clinical Trials Day (Thursday 20 May 2021)

Thousands of volunteers will receive a booster COVID-19 vaccine in a new clinical trial launching today, Health Secretary Matt Hancock has announced.

The Cov-Boost study, led by University Hospital Southampton NHS Foundation Trust and backed by £19.3 million of government funding through the Vaccines Taskforce, will trial seven vaccines and will be the first in the world to provide vital data on the impact of a third dose on patients' immune responses.

It will give scientists from around the globe and the experts behind the UK's COVID-19 vaccination programme a better idea of the impact of a booster dose of each vaccine in protecting individuals from the virus.

The study will take place at 16 NIHR-supported sites across England, and also within Health and Care Research Wales and NHS Research Scotland sites. It will include a total of 2,886 patients and participants are to begin being vaccinated from early June.

All participants will be monitored throughout the study for any side effects and will have bloods taken to measure their immune responses at days 28, 84, 308 and 365, with a small number having additional blood tests at other times. All sites will have an electronic diary for all participants that will send alerts to the team in real time if needed and a 24-hour emergency phone to a doctor on the study, who can provide further clinical advice.

The initial findings, expected in September, will help inform decisions by the Joint Committee on Vaccination and Immunisation (JCVI) on plans for a booster programme from autumn this year, ensuring the country's most vulnerable are given the strongest possible protection over the winter period.

The Health Secretary has also announced that the 2021 G7 Health Ministers' Meeting will be held in-person at Oxford University on 3-4 June. As part of the UK's G7 Presidency, we are bringing together health leaders from the world's leading democracies to agree life-saving action in the critical areas of clinical trials, global health security, antimicrobial resistance, and digital health to help protect us all from future pandemics.

Health and Social Care Secretary, Matt Hancock said:

The UK vaccination programme has been a phenomenal national effort, with seven in 10 UK adults now having had their first COVID-19 jab. It is vital that we continue to support the world-renowned British research sector that has contributed to its success.

We will do everything we can to future-proof this country from pandemics and other threats to our health security, and the data from this world-first clinical trial will help shape the plans for our booster programme later this year.

I urge everyone who has had both doses of a COVID-19 vaccine, and is eligible, to sign up for this study and play a part in protecting the most vulnerable people in this country and around the world for months and years to come.

The trial will look at seven different COVID-19 vaccines as potential boosters, given at least 10 to 12 weeks after a second dose as part of the ongoing vaccination programme. One booster will be provided to each volunteer and could be a different brand to the one they were originally vaccinated with.

Vaccines being trialled include Oxford/AstraZeneca, Pfizer/BioNTech, Moderna, Novavax, Valneva, Janssen and Curevac, as well as a control group. The trial has received ethics approval by the NHS Research Ethics Committee, as well as approval from the Medicines and Healthcare products Regulatory Agency.

The study will open for applications from volunteers shortly via the study's website and will be recruiting participants through the NHS COVID-19 Vaccine Research Registry.

Participants will be adults aged 30 years or older as these will have been those immunised early on in the vaccination programme – for example, adults aged 75 and over or health and care workers.

The trial was commissioned by the Department of Health and Social Care through the National Institute for Health Research (NIHR) and funded by the Vaccine Taskforce, with the study being undertaken by the Southampton team at sites across the UK as part of the National Immunisation Schedule Evaluation Consortium (NISEC).

The team leading the trial is committed to including participants from a wide variety of backgrounds, and individuals from ethnic minorities are encouraged to apply to take part.

Chief Investigator and Director of NIHR Southampton Clinical Research Facility Professor Saul Faust said:

This trial will give the Joint Committee on Vaccination and Immunisation the important data to inform their recommendations of how to protect the population against any future wave.

It is fantastic that so many people across the country have taken part in vaccine trials up to now so that we can be in a position to study the effects of boosters, and we hope that as many people as possible over the age of 30 who received their first dose early in the NHS programme will be able to take part.

The UK's vaccination programme continues at record pace, with over 57.8 million vaccines administered in total – 36.9 million first doses, which amounts to seven in 10 UK adults being given one jab – and 20.8 million second doses, which gives people even stronger protection.

The government is preparing for a booster programme based on clinical need and will publish further details in due course. The final policy will be informed by advice from the JCVI and take into account the results of clinical trials.

Minister for COVID-19 Vaccine Deployment Nadhim Zahawi said:

With over 57 million vaccines administered since the beginning of the rollout, the programme continues its fantastic trajectory.

Having taken part in a COVID-19 vaccine clinical trial myself, I would encourage everyone eligible to volunteer – whatever your religion, ethnicity or background, it's a fantastic opportunity to get involved with such an historic initiative.

Earlier this year, the government announced the launch of the ComCov clinical trial, which aims to determine the effects of using different vaccines for the first and second dose – for example, using Oxford/AstraZeneca's vaccine for the first dose, followed by Pfizer/BioNTech's vaccine for the second.

Initial results from this trial have shown that mixing the doses slightly increases the frequency of mild-to-moderate symptoms following vaccination, but there were no serious outcomes.

Further results from this clinical trial – including on the immune response in people who have two different vaccine doses – are expected over the coming months.

Professor Andrew Ustianowski, National Clinical Lead for the UK NIHR COVID-19

Vaccine Research Programme

Throughout the pandemic, the National Institute for Health Research, the NHS and all of our research partners have helped to rollout vital studies to help us learn how to treat COVID-19 and develop effective vaccines.

The Cov-Boost study marks the next step forward in our efforts of understanding how to best protect the population and inform future vaccine booster programmes.

Since the launch of the NHS COVID-19 Vaccine Research Registry, thousands of volunteers have been recruited to key vaccine studies, and we are confident we can call upon our nearly half a million strong community to help recruitment to this important trial.

Notes to Editors:

About the National Institute for Health Research

The National Institute for Health Research (NIHR) is the nation's largest funder of health and care research. The NIHR:

- Funds, supports and delivers high quality research that benefits the NHS, public health and social care
- Engages and involves patients, carers and the public in order to improve the reach, quality and impact of research
- Attracts, trains and supports the best researchers to tackle the complex health and care challenges of the future
- Invests in world-class infrastructure and a skilled delivery workforce to translate discoveries into improved treatments and services
- Partners with other public funders, charities and industry to maximise the value of research to patients and the economy